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NOTICE OF ALLOWANCE AND FEE(S) DUE

1218 7590 08/14/2009

CASELLA & HESPOS
274 MADISON AVENUE
NEW YORK, NY 10016

EXAMINER

MARCETICH, ADAM M

ART UNIT

PAPER NUMBER

3761

DATE MAILED: 08/14/2009

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/559,700

12/06/2005

Hajime Nakazawa

P1446US

2871

TITLE OF INVENTION: STORAGE CONTAINER AND MEDICAL SUCKING TOOL HAVING THE SAME

APPLN. TYPE	SMALL ENTITY	ISSUE FEE DUE	PUBLICATION FEE DUE	PREV. PAID ISSUE FEE	TOTAL FEE(S) DUE	DATE DUE
nonprovisional	NO	\$1510	\$300	\$0	\$1810	11/16/2009

THE APPLICATION IDENTIFIED ABOVE HAS BEEN EXAMINED AND IS ALLOWED FOR ISSUANCE AS A PATENT. PROSECUTION ON THE MERITS IS CLOSED. THIS NOTICE OF ALLOWANCE IS NOT A GRANT OF PATENT RIGHTS. THIS APPLICATION IS SUBJECT TO WITHDRAWAL FROM ISSUE AT THE INITIATIVE OF THE OFFICE OR UPON PETITION BY THE APPLICANT. SEE 37 CFR 1.313 AND MPEP 1308.

THE ISSUE FEE AND PUBLICATION FEE (IF REQUIRED) MUST BE PAID WITHIN THREE MONTHS FROM THE MAILING DATE OF THIS NOTICE OR THIS APPLICATION SHALL BE REGARDED AS ABANDONED. THIS STATUTORY PERIOD CANNOT BE EXTENDED. SEE 35 U.S.C. 151. THE ISSUE FEE DUE INDICATED ABOVE DOES NOT REFLECT A CREDIT FOR ANY PREVIOUSLY PAID ISSUE FEE IN THIS APPLICATION. IF AN ISSUE FEE HAS PREVIOUSLY BEEN PAID IN THIS APPLICATION (AS SHOWN ABOVE), THE RETURN OF PART B OF THIS FORM WILL BE CONSIDERED A REQUEST TO REAPPLY THE PREVIOUSLY PAID ISSUE FEE TOWARD THE ISSUE FEE NOW DUE.

HOW TO REPLY TO THIS NOTICE:

I. Review the SMALL ENTITY status shown above.

If the SMALL ENTITY is shown as YES, verify your current SMALL ENTITY status:

A. If the status is the same, pay the TOTAL FEE(S) DUE shown above.

B. If the status above is to be removed, check box 5b on Part B - Fee(s) Transmittal and pay the PUBLICATION FEE (if required) and twice the amount of the ISSUE FEE shown above, or

If the SMALL ENTITY is shown as NO:

A. Pay TOTAL FEE(S) DUE shown above, or

B. If applicant claimed SMALL ENTITY status before, or is now claiming SMALL ENTITY status, check box 5a on Part B - Fee(s) Transmittal and pay the PUBLICATION FEE (if required) and 1/2 the ISSUE FEE shown above.

II. PART B - FEE(S) TRANSMITTAL, or its equivalent, must be completed and returned to the United States Patent and Trademark Office (USPTO) with your ISSUE FEE and PUBLICATION FEE (if required). If you are charging the fee(s) to your deposit account, section "4b" of Part B - Fee(s) Transmittal should be completed and an extra copy of the form should be submitted. If an equivalent of Part B is filed, a request to reapply a previously paid issue fee must be clearly made, and delays in processing may occur due to the difficulty in recognizing the paper as an equivalent of Part B.

III. All communications regarding this application must give the application number. Please direct all communications prior to issuance to Mail Stop ISSUE FEE unless advised to the contrary.

IMPORTANT REMINDER: Utility patents issuing on applications filed on or after Dec. 12, 1980 may require payment of maintenance fees. It is patentee's responsibility to ensure timely payment of maintenance fees when due.

PART B - FEE(S) TRANSMITTAL

**Complete and send this form, together with applicable fee(s), to: Mail Mail Stop ISSUE FEE
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INSTRUCTIONS: This form should be used for transmitting the ISSUE FEE and PUBLICATION FEE (if required). Blocks 1 through 5 should be completed where appropriate. All further correspondence including the Patent, advance orders and notification of maintenance fees will be mailed to the current correspondence address as indicated unless corrected below or directed otherwise in Block 1, by (a) specifying a new correspondence address; and/or (b) indicating a separate "FEE ADDRESS" for maintenance fee notifications.

CURRENT CORRESPONDENCE ADDRESS (Note: Use Block 1 for any change of address)

Note: A certificate of mailing can only be used for domestic mailings of the Fee(s) Transmittal. This certificate cannot be used for any other accompanying papers. Each additional paper, such as an assignment or formal drawing, must have its own certificate of mailing or transmission.

1218 7590 08/14/2009

CASELLA & HESPOS
274 MADISON AVENUE
NEW YORK, NY 10016

Certificate of Mailing or Transmission

I hereby certify that this Fee(s) Transmittal is being deposited with the United States Postal Service with sufficient postage for first class mail in an envelope addressed to the Mail Stop ISSUE FEE address above, or being facsimile transmitted to the USPTO (571) 273-2885, on the date indicated below.

(Depositor's name)
(Signature)
(Date)

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/559,700	12/06/2005	Hajime Nakazawa	P1446US	2871

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nonprovisional	NO	\$1510	\$300	\$0	\$1810	11/16/2009

EXAMINER	ART UNIT	CLASS-SUBCLASS
MARCETICH, ADAM M	3761	604-319000

1. Change of correspondence address or indication of "Fee Address" (37 CFR 1.363).

- ☐ Change of correspondence address (or Change of Correspondence Address form PTO/SB/122) attached.
- ☐ "Fee Address" indication (or "Fee Address" Indication form PTO/SB/47; Rev 03-02 or more recent) attached. **Use of a Customer Number is required.**

2. For printing on the patent front page, list

- (1) the names of up to 3 registered patent attorneys or agents OR, alternatively, 1 _____
- (2) the name of a single firm (having as a member a registered attorney or agent) and the names of up to 2 registered patent attorneys or agents. If no name is listed, no name will be printed. 2 _____
- 3 _____

3. ASSIGNEE NAME AND RESIDENCE DATA TO BE PRINTED ON THE PATENT (print or type)

PLEASE NOTE: Unless an assignee is identified below, no assignee data will appear on the patent. If an assignee is identified below, the document has been filed for recordation as set forth in 37 CFR 3.11. Completion of this form is NOT a substitute for filing an assignment.

(A) NAME OF ASSIGNEE (B) RESIDENCE: (CITY and STATE OR COUNTRY)

Please check the appropriate assignee category or categories (will not be printed on the patent) : ☐ Individual ☐ Corporation or other private group entity ☐ Government

4a. The following fee(s) are submitted:

- ☐ Issue Fee
- ☐ Publication Fee (No small entity discount permitted)
- ☐ Advance Order - # of Copies _____

4b. Payment of Fee(s); (Please first reapply any previously paid issue fee shown above)

- ☐ A check is enclosed.
- ☐ Payment by credit card. Form PTO-2038 is attached.
- ☐ The Director is hereby authorized to charge the required fee(s), any deficiency, or credit any overpayment, to Deposit Account Number _____ (enclose an extra copy of this form).

5. Change in Entity Status (from status indicated above)

- ☐ a. Applicant claims SMALL ENTITY status. See 37 CFR 1.27. ☐ b. Applicant is no longer claiming SMALL ENTITY status. See 37 CFR 1.27(g)(2).

NOTE: The Issue Fee and Publication Fee (if required) will not be accepted from anyone other than the applicant; a registered attorney or agent; or the assignee or other party in interest as shown by the records of the United States Patent and Trademark Office.

Authorized Signature _____

Date _____

Typed or printed name _____

Registration No. _____

This collection of information is required by 37 CFR 1.311. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, Virginia 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, Virginia 22313-1450.

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10/559,700	12/06/2005	Hajime Nakazawa	P1446US	2871
1218	7590	08/14/2009	EXAMINER	
CASELLA & HESPOS 274 MADISON AVENUE NEW YORK, NY 10016			MARCETICH, ADAM M	
			ART UNIT	PAPER NUMBER
			3761	
DATE MAILED: 08/14/2009				

Determination of Patent Term Adjustment under 35 U.S.C. 154 (b) (application filed on or after May 29, 2000)

The Patent Term Adjustment to date is 528 day(s). If the issue fee is paid on the date that is three months after the mailing date of this notice and the patent issues on the Tuesday before the date that is 28 weeks (six and a half months) after the mailing date of this notice, the Patent Term Adjustment will be 528 day(s).

If a Continued Prosecution Application (CPA) was filed in the above-identified application, the filing date that determines Patent Term Adjustment is the filing date of the most recent CPA.

Applicant will be able to obtain more detailed information by accessing the Patent Application Information Retrieval (PAIR) WEB site (<http://pair.uspto.gov>).

Any questions regarding the Patent Term Extension or Adjustment determination should be directed to the Office of Patent Legal Administration at (571)-272-7702. Questions relating to issue and publication fee payments should be directed to the Customer Service Center of the Office of Patent Publication at 1-(888)-786-0101 or (571)-272-4200.

Notice of Allowability	Application No.	Applicant(s)	
	10/559,700	NAKAZAWA ET AL.	
	Examiner	Art Unit	
	Adam Marcetich	3761	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to 23 June 2009.
2. ☒ The allowed claim(s) is/are 1,4,5,8,10-13 and 20-25.
3. ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) ☒ All b) ☐ Some* c) ☐ None of the:
 1. ☒ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).
 - * Certified copies not received: _____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.

THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

4. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
5. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
 - (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
 - 1) ☐ hereto or 2) ☐ to Paper No./Mail Date _____.
 - (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____.

Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
6. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

- | | |
|--|--|
| 1. <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 5. <input type="checkbox"/> Notice of Informal Patent Application |
| 2. <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 6. <input type="checkbox"/> Interview Summary (PTO-413),
Paper No./Mail Date _____. |
| 3. <input type="checkbox"/> Information Disclosure Statements (PTO/SB/08),
Paper No./Mail Date _____ | 7. <input checked="" type="checkbox"/> Examiner's Amendment/Comment |
| 4. <input type="checkbox"/> Examiner's Comment Regarding Requirement for Deposit
of Biological Material | 8. <input checked="" type="checkbox"/> Examiner's Statement of Reasons for Allowance |
| | 9. <input type="checkbox"/> Other _____. |

/Adam Marcetich/
Examiner, Art Unit 3761

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 23 June 2009 has been entered.

35 USC § 112, 6th Paragraph

2. Claims 6 and 7 are canceled, therefore 35 USC § 112, 6th Paragraph is no longer invoked for claims 6 and 7.
3. The amendments filed 23 June 2009 remove the language “connection adaptor means,” “waste fluid holding means” and “air discharge means,” therefore 35 USC § 112, 6th Paragraph is no longer invoked for these limitations.
4. Regarding the “clamped portion means” of claim 26, the language appears to be an attempt to invoke 35 USC 112, 6th paragraph interpretation of the claims. A claim limitation will be interpreted to invoke 35 USC 112, 6th paragraph if it meets the following 3-prong analysis:
- (A) The claim limitations must use the phrase “means for” or “step for;”
 - (B) the “means for” or “step for” must be modified by functional language;

and

(C) the phrase “means for” or “step for” must not be modified by sufficient structure, material or acts for achieving the specified function.

If the examiner finds that a prior art element:

(A) performs the function specified in the claim,

(B) is not excluded by any explicit definition provided in the specification for an equivalent, and

(C) is an equivalent of the means- (or step-) plus-function limitation,

then the prior art element may be considered by the examiner to be an equivalent to the means plus function limitation, and the prior art may anticipate the claimed limitation. See MPEP 2183.

5. Regarding claim 26, Applicant appears to have met the requirements set forth in MPEP §2181, and Examiner has turned to the specification for clarification. The specification supports the “clamped portion means” on p. 15, ¶ 3, Fig. 2, clamped portion 32d.

Allowable Claims

6. Claims 1,4,5,8,10-13 and 20-25 are allowed over the prior art of record.

Examiner's Amendment

7. An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided

by 37 CFR 1.312. To ensure consideration of such an amendment, it **MUST** be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Gerald E. Hespos on Tuesday, 11 August 2009.

The application has been amended as follows:

Cancel claim 26.

Reasons For Allowance

8. The following is an examiner's statement of reasons for allowance: the closest prior art of record, Oikarinen et al. (WO 0149344), discloses a receptacle for use with a medical suction device, comprising:

a rigid case for detachably holding and air-tightly surrounding at least a portion of said receptacle (p. 3, lines 14-19, Fig. 4, airtight container 2);

a patient-side tube for introducing waste liquid into said receptacle (p. 3, lines 21-24, Fig. 4, tube (not shown) connected to suction bag 3);

designed to create a negative pressure in both an interior space of said rigid case and an interior space of said receptacle so as to allow waste liquid to be sucked into said receptacle through said patient-side tube (p. 3, lines 14-19, suction inlet 4 for producing underpressure in container 2 and bag 3);

said receptacle comprising:

one port portion or connection adapter connected to said patient-side tube (p. 3, lines 21-24, Fig. 4, tube (not shown) connected to first lead-through means 6);

a receptacle main body for holding waste fluid sucked through the port portion (Fig. 4, body of bag 3);

said receptacle main body having a wall formed of sheets (p. 1, lines 15-16, EP 0861668 incorporated by reference, also published as Greter; Andy (US 6056730), depicts a bag suggested as formed of sheets, see Figs. 1 and 2, bag B of Greter);

an air-pervious/liquid-impervious element having air perviousness and liquid imperviousness (p.3, lines 24-29, Fig. 4, filter 5);

said air-pervious/liquid-impervious being provided in at least the portion of said receptacle main body (p.3, lines 24-29, Fig. 4, filter 5 provided on body of bag 3);

wherein said air-pervious/liquid-impervious element is adapted to discharge air in the interior space of said receptacle to the interior space of said rigid case in response to the negative pressure created in the interior space of said rigid case (Fig. 4, space shown between second lead-through means 7 comprising filter 5 and suction inlet 4);

an outer peripheral portion of said port portion is detachably and air-tightly attachable to said rigid case, so that an entire region except for a part of said port portion is surrounded by said rigid case (p.4, lines 17-28, especially lines 26-28, Fig. 4, first lead-through means 6 extending through clamp 11); and

a guide hole (Fig. 4, lumen extending through first lead-through means 6).

Oikarinen discloses the invention substantially as claimed, see above. However, Oikarinen lacks a check valve within a port portion.

9. Olson (US 5275585) discloses a receptacle and rigid case for medical suction (col. 2, lines 47-52, col. 3, lines 15-30, Fig. 1, autotransfusion system 10 comprising collection bag 26 and rigid receptacle 16), further comprising:

a check valve adapted to allow waste liquid sucked from said patient-side tube to flow into the interior space thereof (col. 3, lines 51-64, especially lines 57-59, Figs. 4-5, suction port 46 and exhaust port 48 both comprising one-way valves not depicted); and

prevent said sucked waste liquid from flowing out to said patient-side tube (it is the Examiner's position that check valves limit backwards flow from collection bag 26 within rigid receptacle 16 as depicted). One would be motivated to modify Oikarinen with the check valve as taught by Olson to prevent reflux since both blood and medical waste fluids are sources of contamination and need to be securely contained.

Oikarinen in view of Olson discloses the invention substantially as claimed, see above. However, Oikarinen in view of Olson lacks a receptacle main body having a folded portion that is located at a height position equal to or above said port portion, and also lacks an air-pervious/impervious element is located at a position below said port portion as amended.

Oikarinen in view of Olson fails to teach or fairly suggest alone or in combination the claimed folded portion or position of an air-pervious/impervious element. The claimed folding structure is critical since it reduces residual pressure within a receptacle after the receptacle has been filled (specification, p. 25, ¶ 5). Also, placing an air-pervious/impervious element below a port portion is critical since the element requires

contact with fluid in order to become air-impervious. In other words, placing the element above a port portion would prevent its contact with fluid when the receptacle is filled.

10. Similarly, Verkaart (US Patent 4,466,888) discloses a blood collection assembly having a rigid outer case and inner flexible bag (col. 3, lines 48-52, 59-65; Figs. 1-3, shells 20 and 22 and collection bag 30) further comprising:

an air- pervious/liquid-impervious element located at a height position equal to or above a port portion (col. 5, lines 3-36, especially lines 9-14, 33-36; Fig. 4, filter 70 extending both above and below inlet port 80).

Verkaart, fails to teach or fairly suggest alone or in combination the essential structures of the claimed device, namely the claimed folding structure.

11. Also made of reference, Keogh; Alan P. et al. (US 5669892) discloses a suction drainage system that prevents overfill (col. 2, lines 9-16) comprising a rigid container and receptacle (col. 3, lines 14-28, Fig. 1, rigid container 12 and collection chamber 20), further comprising:

pressure reduction means for reducing a residual pressure in a receptacle main body (col. 4, lines 1-23, especially lines 12-17, Fig. 2, overfill protection sleeve 40; col. 4, lines 24-34, additional clearance of sleeve 40 providing “give” during capping and removal of chamber 20). However, Keogh does not fold sleeve 40. therefore, Keogh also fails to teach or fairly suggest alone or in combination the essential structures of the claimed device, namely the claimed folding structure.

12. Not previously made of reference, Villari; Frank K. (US 4187860) discloses an arterial blood collection device (col. 2, lines 39-43, Figs. 1-3, device 10), further comprising:

a rigid case (col. 2, lines 39-43, Figs. 1-3, housing 12); and
a receptacle main body for collecting fluids (col. 2, lines 39-43, Figs. 1-3, expansible collection bag 16).

Villari expands bag 16 by rolling (col. 3, lines 57-65, Figs. 3, 4). However, Villari is directed to blood collection and does not reduce pressure within housing 12. Instead, bag 16 expands in response to normal arterial pressure (col. 3, lines 57-65).

Additionally, Villari is incompatible with an air-pervious/impervious element, since blood is collected by arterial pressure and not under vacuum. Therefore, one would not look to Villari to remedy the deficiencies of by folding a top portion of a bag as amended.

13. Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

14. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

- | | |
|-------------------------------|----------------|
| ◆ Schurer; Friedrich | US 2999500 |
| ◆ Gortz; Norman et al. | US 3767078 |
| ◆ Kurtz; Leonard D. et al. | US 4500308 |
| ◆ Lockwood, Jeffrey S. et al. | US 20030014022 |
| ◆ Deaton; David W. et al. | US 3945392 |

15. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Adam Marcetich whose telephone number is 571-272-2590. The examiner can normally be reached on 8:00am to 4:00pm Monday through Friday.

16. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Tatyana Zalukaeva can be reached on 571-272-1115. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 3761

17. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Adam Marcetich/
Examiner, Art Unit 3761

/Leslie R. Deak/
Primary Examiner, Art Unit 3761
11 August 2009